

REMARKS

The present application relates to inbred maize line PH51H. Claims 2-75 have been canceled. Claims 17-20, 31-33, 36, 43-46, and 48-51 were previously canceled in the Amendment filed June 12, 2003 and claims 44-46 and 50-51 were previously canceled in the Amendment of December 13, 2002. New claims 76-105 have been added. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

Detailed Action

A. Claim and Specification Objections

Applicant acknowledges the rejection of claims 22, 30-33, and 47-49 under 35 U.S.C. § 112, second paragraph are withdrawn in light of the previous claim amendments or cancellations. The rejection of claims 9, 10, 14, 17, 22, 28, 29, 32, 33, 36, 41, and 43 under 35 U.S.C. §§ 102(e)/103(a) are acknowledged as withdrawn upon further consideration.

The Examiner objects to claims 8 and 27 under 37 C.F.R. § 1.75(c) as being of improper dependent form. Applicant has canceled claims 8 and 27, thereby making this objection moot.

B. Newly Submitted Claims

Applicant acknowledges the addition of new claims 76 through 105, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and revised via telephone on August 25, 2003 and September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification. Support for the specific items noted in the claims faxed by Examiner Fox can be found within the specification for *Bacillus thuringiensis* on page 27; for imidazolinone, sulfonylurea, glyphosate, glufosinate, L-phosphinothricin, triazine, and benzonitrile on pages 30-31; for phytase on page 31; for stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase and starch branching enzyme on pages 31-32; and for waxy starch and increased amylose starch on pages 20 and 32. In addition, Applicant has amended the specification to clarify the deposit language.

No new matter has been added by the present amendment. Entry of this Amendment and approval of the changes is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 6, 11-13, 15, 16, 25, 34, 35, and 52-75 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 6 and 25 are indefinite for the recitation "capable of expressing". The Examiner states it is not clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed..

Applicant has canceled claims 6 and 25 and added new claims 81 and 98 to include the language --having--, as suggested by the Examiner, thus alleviating this rejection.

The Examiner rejects claim 11 as indefinite for the recitation "comprises contains" in line 3 as it is not clear what the recitation encompasses.

Applicant has now canceled claim 11, thereby alleviating this rejection.

Claims 15 and 34 are indefinite because the last step of the claim is inconsistent with the preamble.

Applicant has canceled claims 15 and 34, alleviating this rejection.

The Examiner rejects claims 52, 57, 62, 66, and 71 as indefinite for the recitation "A method of making a PH51H plant" in line 1 of the claims.

Although not acceding to the Examiner's rejection, in order to expedite prosecution Applicant has now canceled claims 52, 57, 62, 66, and 71, thus rendering this rejection moot.

Claims 55, 60, 64, 69, and 73 stand rejected as indefinite for the recitation "comprising the method of claim 52(or 57 or 62 or 66 or 71) and further comprising crossing the PH51H maize plant of claim 52 with a second maize plant".

Applicant has canceled claims 55, 60, 64, 69, and 73, thereby alleviating this rejection.

The Examiner rejects claim 68 as indefinite for the recitation "a cytoplasm that confers male sterility".

Applicant has now canceled claim 69, alleviating this rejection.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 9-16, 22, 28-30, 34, 35, 37-39, 41, 42 and 47 remain and claims 52-75 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in the Office Action mailed March 12, 2003.

The Applicant traverses the rejection. Although not acceding to the Examiner's rejection, to expedite prosecution Applicant has canceled claims 2-75, thereby rendering this rejection moot. Applicant has added new claims 76-105, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and August 25, 2003 and September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification as described *supra*.

Claims 11-13, 22, 30, 47, and 52-75 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner further states it is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. The Examiner also asserts that Hunsperger *et al.*, Kraft *et al.*, and Eshed *et al.* teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype is said different plant.

Applicant respectfully traverses this rejection. The Applicant has provided assurance that at least 2500 seeds of inbred maize line PH51H have been deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02). Although not acceding to the Examiner's rejection, to expedite prosecution Applicant has canceled claims 11-13, 22, 30, 47, and 52-75, thereby rendering this rejection moot. Applicant has added new claims 76-105, as disclosed *supra*. It is respectfully submitted that Applicant's claims are sufficiently described and enabled by the specification.

In addition, Applicant asserts that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested material. An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation.

Further, the Applicant would like to reiterate that a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601.

The Applicant also respectfully disagrees with the Examiner as to what is taught by Hunsperger *et al.* Hunsperger *et al.* merely teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger *et al.* merely discusses that the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger *et al.* succeeded in incorporating the gene into petunia plants of different genetic backgrounds. In fact, the USPTO in Hunsperger *et al.* allowed claims to any petunia plant comprising genes for dwarfism. Therefore, Hunsperger *et al.* supports the fact that one can introgress a specific trait into a recurrent parent through backcross conversion. Applicant's specification provides ample disclosure of starting materials such as, maize inbred line PH51H, a discussion of traditional breeding methods, and examples of transgenes and naturally occurring genes that may be used in such methods. Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, states that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." The teaching of Hallauer *et al.* relates specifically to corn breeding and corn inbred line development.

The Examiner goes on to state that, "Kraft *et al.* teaches that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-dependent in nature" (page 323, column 1, lines 7-15). Applicant disagrees that the article states such points. Kraft *et al.* makes no mention of a plant comprising a single gene conversion or the use of backcrossing. Further,

Kraft *et al.* relates to linkage disequilibrium and fingerprinting in sugar beet, a crop other than maize. Kraft *et al.* states, on page 326, first column, "The generality of our results for other crop species needs to be investigated."

It is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on its web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple backcrossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, "essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering."

The Examiner goes on to state that, "Eshed *et al.* teaches that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in genetically complex and less than additive fashion" (page 1815, column 1, line 1 to page 1816, column 1, line 1). The Applicant would like to point out on page 1816, column 1, lines 1-5 of the Eshed *et al.* article it states, "Recent studies that detected epistasis of selected QTL in *Drosophila* (Long *et al.* 1995), soybean (Lark *et al.* 1995) and maize (Doebley *et al.* 1995; Cockerham and Zeng 1996) did not show a less-than-additive trend." Emphasis added. The Applicant also adds that transferring a qualitative trait does not require undue experimentation. Please note Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." In newly submitted claims 76-105, the genes transferred into PH51H are now limited to the traits of disease resistance, insect resistance, herbicide resistance, male sterility, waxy starch, and a nucleic acid molecule that encodes an enzyme that modifies fatty acid metabolism, phytic acid metabolism or carbohydrate metabolism. Applicant respectfully requests the Examiner to withdraw this rejection. For the reasons aforementioned, it is respectfully submitted that Applicant's claims are sufficiently described and enabled by the specification.

In light of the above amendments and remarks, Applicant respectfully requests withdrawal of the rejections to claims 9-16, 22, 28-30, 34, 35, 37-39, 41, 42, 47 and 52-75 under 35 U.S.C. § 112, first paragraph.

Summary

Applicant acknowledges that claims 1-5, 7, 21, 23, 24, 26, and 40 are allowed.

Applicant has amended the claims as suggested by Examiner David Fox and Supervisory Patent Examiner Amy Nelson as allowable. Applicant submits the claims place the application in condition for allowance and comply with all requirements of form set forth in previous office actions.

Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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